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October 20, 2023

VIA ECF

The Honorable Denise Cote
United States District Court
for the Southern District of New York
Daniel Patrick Moynihan
United States Courthouse
500 Pearl Street
New York, NY 10007-1312

RE: *In re Acetaminophen ASD/ADHD Products Liability Litig.*, No. 1:22-md-3043 (DLC)

Dear Judge Cote:

I am writing to apologize for an error that resulted in defendants citing an outdated valproic acid label in their response to plaintiffs' *Daubert* motions. The error occurred because a member of my team pulled an older label from the FDA website, and I did not catch it. Although it was inadvertent, I take full responsibility for the mistake.

That said, the error does not materially affect defendants' arguments. Indeed, plaintiffs' reply brief in support of their Motion to Exclude the Opinions of Dr. Jennifer Pinto-Martin spends more time criticizing defendants for the error than explaining its significance to the *Daubert* question.

Plaintiffs rely on the label to assert that the valproic acid label demonstrates that there might be environmental causes for autism spectrum disorder ("ASD") and attention deficit hyperactivity disorder ("ADHD"). (Pinto-Martin Reply at 5.) Defendants' experts' position is not to the contrary; rather, defendants' experts have opined that: (1) the vast majority of ASD and ADHD cases have genetic causes; and

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(2) plaintiffs' experts lack sufficient scientific support for the conclusion that acetaminophen is one of the few non-genetic causes.

Plaintiffs also assert that the valproic acid warning label supports the admissibility of their experts' opinions because the causation evidence with respect to that medication is "comparable [to] (and arguably much weaker)" than the evidence in the case of acetaminophen. (Pinto-Martin Reply at 5-6.) But that is not correct. As Dr. Pinto-Martin explains, "[t]he data establishing association between ASD and valproic acid is considerably more robust than the data on prenatal acetaminophen exposure. The association is stronger and more consistent, and researchers have much more precise information on exposure." (Rep. of Jennifer Pinto-Martin at 35, July 21, 2023.) Defendants' brief in opposition to the motion to exclude her testimony made the same points. (*See* ECF 1241, at 35.)

In any event, "the FDA often uses a different standard than a court does to evaluate evidence of causation in a products liability action" and "may choose to err on the side of caution . . . upon a lesser showing of harm to the public than the preponderance-of-the-evidence . . . standard" *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 387 F. Supp. 3d 323, 356 (S.D.N.Y. 2019). To the extent the FDA believed that standard was satisfied for valproic acid, it stands in strong contrast to its view on acetaminophen—i.e., that it is "unable to support a determination of causality." (*See* ECF 1105, at 2 ("FDA Letter")) (citation omitted.)

Again, please accept my apology for the reference to and argument based on an outdated valproic acid label. I regret any trouble that it has caused the Court or plaintiffs.

Respectfully submitted,

A handwritten signature in cursive script that reads "Jessica Davidson".

Jessica Davidson